

June 11, 1997

K970934

510(k) Summary

Submitter: Continuum Biomedical, Inc.
6533 Sierra Lane
Dublin, CA 94568

Contact: Robert S. Anderson, Ph.D.
President

Date Summary Prepared: March 13, 1997

Device Trade Name: CB Erbium / 2.94TM Er:YAG Laser

Common Name: Medical laser system

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device: Schwartz Electro-Optics TriLase 2940
Coherent UltraPulse CO₂ Laser

Device Description: CB Erbium / 2.94TM Er:YAG Laser consists of three interconnected sections: the power supply, the water cooling system and the optical bench. At 5 pulses per second and a pulse energy of 2 Joules, the average power from the laser is 10 watts.

Intended Use: For skin resurfacing in the treatment of wrinkles

Comparison: CB Erbium / 2.94TM Er:YAG Laser provides comparable results as the CO₂ laser for the treatment of wrinkles, with fewer side effects and faster recovery time.

Nonclinical Performance Data: none

Clinical Performance Data: A clinical trial was conducted using a side by side comparison of the CB Erbium / 2.94TM Er:YAG and a CO₂ laser. The reduction of wrinkles was comparable for both lasers with notably few side effects and faster recovery time with the CB Erbium / 2.94TM Er:YAG Laser.

Conclusion: The CB Erbium / 2.94TM Er:YAG Laser is another safe and effective way to remove or reduce facial wrinkles.

Additional Information: None requested at this time.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Ms. Laurie A. Ridener
Regulatory Affairs Officer
Continuum Biomedical, Inc.
6533 Sierra Lane
Dublin, California 94568

*
Re: K970934
Trade Name: CB Erbium 2.94TM Er:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: March 13, 1997
Received: March 13, 1997

Dear Ms. Ridener:

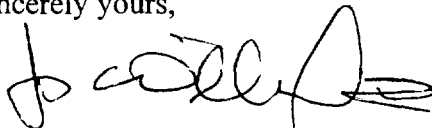
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K970934

510(k) Number (if known): *pending*
Device Name: CB Erbium / 2.94TM Er:YAG Laser
Indications for Use: For skin resurfacing in the treatment of wrinkles

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970934

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)